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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,704	05/30/2000	George Peter Lomonossoff	DOW-04647	2167

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EXAMINER

AKHAVAN, RAMIN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/580,704

Applicant(s)

LOMONOSSOFF ET AL.

Examiner

Ramin (Ray) Akhavan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-9 and 12-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-9 and 12-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

An amendment filed 04/26/2004 is acknowledged. As a result, claims 1, 9 and 12-16 are amended. It is also noted that applicant refers to claims 1-16 as pending (e.g. Remarks page 1; see also, page 8; noting the possibility of claims 1-8 to issue and splitting out claims 9-16). Claims 2-3 and 10-11 were cancelled in an amendment filed 08/13/2003, pursuant to applicant's submission. Claims 1, 4-9 and 12-16 are pending and under consideration in this action.

Applicant's request for consultation with respect to the possibility of "split[ting] out claims 9-16 into a separate application" is acknowledged, in regard to the double patenting rejections made in the previous action. However, as other rejections are maintained (as discussed below), an action is respectfully submitted without prior phone consultation. Any objections or rejections not repeated herein are withdrawn. This action is non-final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 1. Claims 1 and 4-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Base claim 1 recites the phrase, "a nucleotide sequence ...inserted *in* plant viral genomic nucleic acid that codes for an expressed native portion of the plant viral coat protein...".

(Emphasis added). As written, the claim is ambiguous and unclear, thus making the claim's metes and bounds indeterminable. As written, it is unclear whether the claim is to be interpreted

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to mean that the foreign nucleotide sequence inserted anywhere “in plant viral genomic nucleic acid”, as long as the genomic nucleic acid encodes “an expressed native portion...of...coat protein...”. From the full disclosure it is evident that the heterologous sequence is to be inserted *into* a precise location of the sequence encoding the coat protein. It would be remedial to replace “in” with “into”.

In addition, base claim 1 recites, “wherein said plant contains assembled modified plant virus.” The claim, as written, is vague and ambiguous as to the source of the “assembled...virus”. For example, a plant could be infected with one virus, which replicates and is infectious and this assembled virus can be wholly distinct from the virus comprising the modified coat protein. It is evident from the disclosure that this is not the interpretation that is intended, but as written the claim’s metes and bounds are indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The claims are drawn to a plant infected with a modified plant virus, where a foreign peptide from an animal virus is inserted in the plant viral genomic nucleic acid that codes for an expressed native portion of the plant viral coat protein, wherein the plant contains assembled modified plant virus. This limitation is interpreted as broadly as reasonable, so that the foreign nucleotide sequence is placed “in” plant viral genomic nucleic acid that encodes for any native

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portion of plant viral coat protein. (See supra, § 112 ¶ 2 Rejection). In addition the claims are drawn to a method of producing modified plant virus, particularly RNA virus, more particularly comovirus. Furthermore, the foreign nucleotide sequence can be from HIV, human rhinovirus or Foot and Mouth disease virus. Similar to base claim 1, base claim 9 is interpreted as broadly as reasonable. Claim 9 recites that the foreign nucleotide sequence is introduced “at that part of [the] plant viral genome that codes for an expressed native portion of the viral coat protein.” Therefore, the broadest reasonable interpretation is not exclusive to insertion *into* native functional coat protein.

2. Claims 1, 4-9 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donson et al. (US 5,316,931; of record; hereinafter ‘931 patent), and further in view of Utermohlen (US 5,437,976; of record; hereinafter ‘976).

The ‘931 patent teaches a plant infected with a modified plant virus (e.g. col. 6, ll. 35-47). A foreign nucleic acid of interest may be inserted into the plant virus genomic nucleic acid that necessarily encodes a portion of plant viral coat protein. (e.g. col. 8, ll. 37-55). Furthermore, the foreign nucleotide sequence can be inserted into or adjacent the native coat protein sequence such that a fusion protein is produced. (e.g. col. 12, ll. 5-12). The plant virus may be RNA virus, or may be comovirus. (e.g. col. 2, ll. 15-45; col. 9, ll. 14-27). Modified plant virus particles are used to infect plants in a method of producing modified plant virus. (e.g. col. 4, ll. 26-43; col. 6, ll. 35-47).

The ‘931 patent does not teach that the foreign peptide encoded by the foreign nucleic acid is from an animal virus.

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The '976 patent teaches the selection of nucleotide sequences from animal viruses in developing vaccines. (e.g. col. 4, ll. 8-25). Various sources for such nucleotide sequences, including Foot and Mouth disease virus, HIV and human rhinovirus are taught. (e.g. col. 6 bridging to col. 7).

The '931 provides motivation to include nucleotide sequences from animal virus in the method of producing modified plant virus, because it explicitly states that it is desirable to use the modified plant virus to produce vaccines. (e.g. col. 14, 59-68). Therefore, it would have been obvious to the skilled artisan to include animal viral sequences as a source of foreign nucleotide sequences in a method of producing modified plant virus. One of ordinary skill in the art would have been motivated to combine the animal virus sources as taught by the '976 patent with the modified plant virus comprising foreign nucleotide sequences as taught by the '931 patent for the expressed result of producing a wide array of vaccines. One of skill in the art would have had a reasonable expectation of success for expressing such foreign nucleotide sequences using modified plant virus.

Response to Arguments

Applicant's argument is centered on the assertion that the '931 patent cannot be used as art, but the argument is not deemed persuasive. Applicant asserts that the parent application (No. 07/600,244; hereinafter '244 application) does not teach insertion of a foreign nucleotide sequence into a native coat protein, thus contending that the '931 patent's priority date is July 31, 1992 and not the '244 application's filing date, Oct. 22, 1990. Applicant's contention is that the parent application only teaches *deleting* or *altering* the coat protein sequence. (Remarks, p. 6,

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bottom). Furthermore, applicant asserts that the '244 application's disclosure does not teach insertion into the native coat protein. (Id., continuation ¶).

From the outset it should be noted that the instant claims, as written, are not so limited (i.e. insertion into sequence encoding functional coat proteins), because the claims are interpreted as broadly as reasonable.

Notwithstanding, the claims' actual limitations, the parent application clearly indicates that foreign nucleotide sequences can be inserted near or at the sequences that encode a portion of the viral coat protein. For example, the '244 application states that a second sequence (i.e. foreign nucleotide sequence) can be placed adjacent to a viral promoter to produce a fusion protein having biological activity. ('244 Specification, p. 27, ll. 10-12; this document is already of record and in applicant's possession). One of skill in the art would recognize that a fusion protein means the foreign nucleotide sequence is inserted into the viral genomic sequence. Furthermore, the '244 application teaches that coat protein can be altered *or* deleted and that in instances where the coat protein is *altered* the second sequence can be *inserted into or adjacent the coat protein coding sequence such that a fusion protein is produced*. (Emphasis added; Id. ll. 17-20). The passage when taken in context in totality with respect to fusion proteins and foreign nucleotide sequences, teaches that a fusion protein is formed and that the fusion protein may have biological activity (i.e. functionality). The '244 application goes on at length to explicitly define biological functionality versus non-functionality ('244 application, pp. 7-8). Applicant chooses to interpret the term "altered" as to mean that the coat protein can by no means be functional. However, this interpretation is simply not borne out of what is disclosed in the '244 application. Applicant does not proffer any additional rebuttals or arguments. Therefore, the

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'931 patent's priority date precedes instant application and the reference is appropriately used as prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. **Claims 9 and 12-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,874,087.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 9 and 12-16 are drawn to a genus of a method of producing a modified plant virus, while reference claims 1-9 are drawn to a species of a method of producing a modified plant virus. Species claims necessarily make obvious the broader genus claims.

4. **Claims 9 and 12-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-28 of U.S. Patent No. 5,958,422.**

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The same analysis as above applies here. The genus claims are necessarily made obvious by the species claims.

Response to Arguments

No arguments have been presented with respect to the Double Patenting rejections.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramin (Ray) Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached on Monday- Friday from 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ray Akhavan
AU 1636


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PRIMARY EXAMINER